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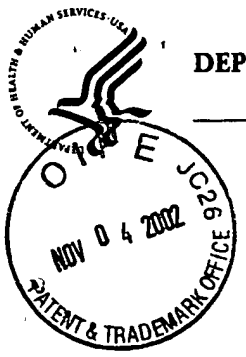

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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OFFICE OF PETITIONS

Re: Lotronex
Docket No.: 01E-0420

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

OCT 3 1 2002

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,360,800, filed by Glaxo Wellcome Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lotronex, the human drug product claimed by the patent.

The total length of the regulatory review period for Lotronex is 3,564 days. Of this time, 3,339 days occurred during the testing phase and 225 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 10, 1990.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 10, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 30, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Lotronex (NDA 21-107) was initially submitted on June 30, 1999.

3. The date the application was approved: February 9, 2000.

   FDA has verified the applicant's claim that NDA 21-107 was approved on February 9, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: David J. Levy, Ph.D.
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